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Please type a plus sign (+) inside this box ☐**UTILITY
PATENT APPLICATION
TRANSMITTAL**

Attorney Docket No.

23925-4

Total Pages

26

First Named Inventor: Paul T. Gardiner

Title: Food Supplement for Increasing Lean Mass and Strength

Express Mail Label No.

EL528222672US

(Only for new nonprovisional applications under 37 CFR 1.53(b))

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

Assistant Commissioner for Patents

**ADDRESSED TO: Box Patent Application
Washington, DC 20231**

1. ☒ Utility Patent Application Transmittal
[Total Pages: 2]
2. ☒ Specification, Claims and Abstract
[Total Pages: 21]
3. ☐ Drawing(s) (35 USC 113) [Total Sheets:]
4. Oath or Declaration [Total Pages: 3]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 21 completed) [Note Box 5 below]
 - i. ☐ **DELETION OF INVENTORS**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference (useable if Box 4b is checked) The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. ☐ Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer readable copy
 - b. ☐ Paper copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

Accompanying Application Parts

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney (when there is an assignee)
10. ☐ English Translation Document (if applicable)
11. ☐ Information Disclosure Statement (IDS/PTO-1449)
 - ☐ Copies of Citations
12. ☒ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
14. ☒ Two Small Entity Statement: 1) Independent Inventor; 2) Small Business Concern
 - ☐ Statement(s) filed in prior application, Status still proper and desired
15. ☐ Certified Copy of Priority Document(s)
16. ☐ Other: _____

17. FEE CALCULATION

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS (37 CFR 1.16(c))	57 -20 =	37	x \$18 =	\$ 740.00
	INDEPENDENT CLAIMS (37 CFR 1.16(b))	14 -3 =	11	x \$78 =	\$ 858.00
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))			+ \$ _____ =	
				BASIC FEE (37 CFR 1.16(a))	690.00
				Total of above Calculations =	\$2288.00
	Reduction by 50% for filing by small entity (Note 37 CFR 1.19, 1.27, 1.28)				\$1144.00
	TOTAL =				\$1144.00

18. ☐ Please charge Deposit Account No. 04-1133 in the amount of \$ _____.
19. ☒ A check in the amount of \$1,144.00 is enclosed.
20. ☒ The Commissioner is hereby authorized to credit overpayments or charge the following fees to Deposit Account No. 04-1133:
- a. ☐ Fees required under 37 CFR 1.16
 - b. ☐ Fees required under 37 CFR 1.17.
 - c. ☐ Fees required under 37 CFR 1.18.

21. **If a CONTINUING APPLICATION**, check appropriate box and supply the requisite information:

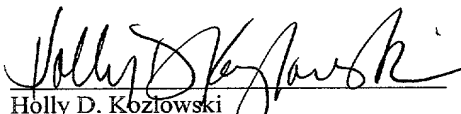
- ☐ Continuation ☐ Divisional ☒ Continuation-in-part (CIP) of prior application No. 09/420,439, filed October 18, 1999.

22. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label or ☒ Correspondence Address Below

Name	Holly D. Kozlowski				
	Dinsmore & Shohl LLP				
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	255 East Fifth Street				
City	Cincinnati	State	OH	Zip Code	45202
Country	USA	Telephone	513-977-8568	Fax	513-977-8141

Respectfully submitted,



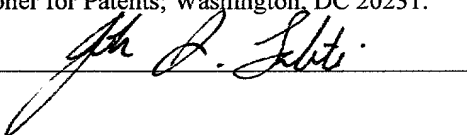
Holly D. Kozlowski
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 1900 Chemed Center
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CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label #: EL528222672US

Date of Deposit: January 13, 1999

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521990.01

Attorney's Docket No: _____

Applicant or Patentee: Paul T. Gardiner, Derek E. Woodgate, Mark S. Gilbert, Robert W. Thoburn
 Serial or Patent No.: _____
 Filed or Issued: _____
 For: Food Supplement For Increasing Lean Mass and Strength

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27 (c)) - SMALL BUSINESS CONCERN

I hereby declare that I am

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN MuscleTech Research and Development Inc.
 ADDRESS OF CONCERN 7050 Telford Way, Unit 100, Mississauga, Ontario, L5S 1V7, Canada

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled Food Supplement For Increasing Lean Mass and Strength by inventors Paul T. Gardiner, Derek E. Woodgate, Mark S. Gilbert, Robert W. Thoburn described in

- ☒ the specification filed herewith
☐ PCT application serial no. filed
☐ patent no. issued

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME _____
 ADDRESS _____
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING TERRY BEGLEY
 TITLE OF PERSON OTHER THAN OWNER VICE-PRESIDENT
 ADDRESS OF PERSON SIGNING 2 RIDELLE COURT, RAMPTON, ONT., CANADA
 SIGNATURE [Signature] DATE Dec 14/99

Attorney's Docket No.: _____

Applicant or Patentee: Paul T. Gardiner, Derek E. Woodgate, Mark S. Gilbert, Robert W. Thoburn
 Serial or Patent No.: _____
 Filed or Issued: _____
 For: Food Supplement For Increasing Lean Mass and Strength

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled described Food Supplement For Increasing Lean Mass and Strength in

☒ the specification filed herewith
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☐ no such person, concern, or organization
☒ persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME Muscletech Research and Development Inc.
 ADDRESS 7050 Telford Way, Unit 100, Mississauga, Ontario, L5S 1V7, Canada
☐ INDIVIDUAL ☒ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Paul T. Gardiner
 Name of Inventor

Paul Gardiner
 Signature of Inventor

Dec 14/99
 Date

Derek E. Woodgate
 Name of Inventor

Derek Woodgate
 Signature of Inventor

14/12/99
 Date

Mark S. Gilbert
 Name of Inventor

Mark S. Gilbert
 Signature of Inventor

Dec 14/99
 Date

Robert W. Thoburn
 Name of Inventor

 Signature of Inventor

 Date

Docket No. 23925-4

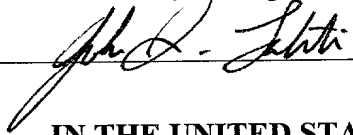
PATENT

CERTIFICATE OF MAILING

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Paul T. Gardiner et al : Paper No.:
Serial No. To be assigned : Group Art Unit:
Filing Date: January 13, 2000 : Examiner:
For: **Food Supplement for Increasing Lean Mass and Strength**

PRELIMINARY AMENDMENT

BOX Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

Prior to calculation of the filing fee and first action by the Examiner, please amend the present application as follows:

In the Specification:

Before line 3, please insert the following:

--RELATED APPLICATION

This application is a continuation in part of prior U.S. Application Serial No. 09/420,439 filed October 18, 1999.--.

In the Claims:

Please amend claims 13, 24 and 57 as follows:

13. (Amended) A supplement according to claim 1 [any one of claims 1 to 12] wherein the source of amino acids is selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, and whey protein.

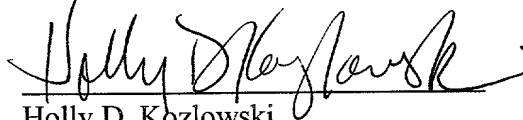
24. (Amended) A food supplement according to claim 19 [anyone of claims 19-23] wherein the source of amino acids is whey protein.

57. (Amended) A method according to claim 52 [anyone of claims 52-56] wherein the source of amino acids is whey protein.

REMARKS

By the present Amendment, the specification is amended to refer to the priority application under 35 U.S.C. §120 and the claims are amended to omit their multiple dependency. Since these changes do not involve any introduction of new matter, entry is believed to be in order and is respectfully requested.

Respectfully submitted,



Holly D. Kozlowski
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Cincinnati, Ohio 45202
(513) 977-8568

522025.01

Title: FOOD SUPPLEMENT FOR INCREASING LEAN MASS AND STRENGTH

FIELD OF INVENTION

5 The present invention is directed to food supplements which
comprise nitric oxide or derivatives thereof, and a source of amino
acids or derivatives thereof; supplements which stimulate nitric
oxide in the body, and a source of amino acids; supplements which
enhance and mimic insulin activity; and to methods for
supplementing the diet of an athlete and methods for enhancing an
10 athlete's muscle size and/or strength, which methods employ these
food supplements.

BACKGROUND OF INVENTION

Food supplements for enhancing an athlete's muscle size and
strength have become popular substitutes for steroids and other drugs
15 in various sports and body building regimes. However, as athletes
continually strive for improved performance, there is a continuing
need for non-steroid containing aids for increasing lean mass, muscle
size and strength.

SUMMARY OF THE INVENTION

20 Nitric oxide plays an essential role in tonic and
exercise-associated (e.g., recovery from exercise) regulation of
vasodilation and blood flow. The present inventor has found that
increased NO through supplementing the diet of an athlete with
substances which increase the concentration of nitric oxide (NO) or
25 increase its half life in the body, in combination with a source of
amino acids, may provide surprising enhancement of an athlete's
muscle size or strength when administered to an athlete's diet.
Accordingly, in one broad aspect the present invention provides new
food supplements to increase the delivery and duration of nitric oxide
30 in the body. These food supplements do not themselves contain nitric
oxide; rather, they act to promote the production of nitric oxide or to
enhance its half life in the body. Preferably the invention provides

food supplements particularly adapted for supplementing the diet of an athlete, preferably the food supplements of the present invention enhance an athlete's muscle size and/or strength.

According to one embodiment of the present invention there is
5 provided a food supplement comprising a substance which increases nitric oxide production in the body, and, a source of amino acids.

Preferably the substance which increases nitric oxide production may act by stimulating insulin levels in the circulation, and, a source of amino acids.

10 According to another preferred embodiment, the supplements of the present invention include a substance which may increase insulin sensitivity, and, a source of amino acids.

According to yet another aspect of the present invention, there
15 is provided a supplement which may increase nitric oxide and thereby increase nitrogen retention in the body. Preferably the supplement comprises a substance which may increase nitrogen retention in the body, in combination with a source of amino acids.

In another aspect, the present invention provides a food
20 supplement comprising a substance which enhances and mimics insulin activity, and, a source of amino acids.

In another broad aspect, the present invention provides
25 methods of supplementing bodybuilding in an athlete comprising administering to the athlete an effective amount of a food supplement according to the present invention to achieve an increase in muscle size and strength. Other features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred
30 embodiments of the invention are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

DETAILED DESCRIPTION OF THE INVENTION

The food supplements and methods of the present invention may provide further and significant muscle size and strength enhancement or improvement in individuals as compared with
5 supplements and methods employing only proteins and/or amino acids. While it is expected that the supplements and methods of the present invention will be of importance to bodybuilders and other athletes, the supplements and methods of the invention are not limited to those groups. Rather, any individual may use the
10 supplements and methods of the invention. Indeed, the supplements and methods may have applications to all animals.

Although the present invention is not to be limited by any theoretical explanation, it is believed that nitric oxide plays an essential role in tonic and exercise-associated (e.g., recovery from
15 exercise) regulation of vasodilation and blood flow. Increased NO supports improved perfusion of skeletal muscle, which it is believed thereby stimulates oxidative metabolism, ATP and creatine phosphate biosynthesis, nutrient (e.g., amino acid) delivery and utilization for muscle (e.g., myofibrillar) protein synthesis, glucose delivery and
20 uptake, glycogen synthesis, creatine delivery and uptake, creatine phosphate synthesis, fat loss regulation of nutrient-mediated insulin secretion, and nitrogen retention. The supplements according to the present invention are preferably based on a unique whey-protein system fortified with additional amino acids to further enhance the
25 rapid absorption (i.e., of (-amino nitrogen) characteristics of whey which lend to its potent protein anabolic effects. Thus, combined with the metabolic effects of increased NO function, the supplements of the present invention effectively enhance the muscle protein anabolic effects of a source of amino acids, preferably any source of protein,
30 more preferably whey.

The food supplements and methods of the present invention may provide further and significant size and strength enhancement

through the role of certain substances which mimic and/or increase the sensitivity of insulin, in conjunction with a source of amino acid. Although the present invention is not to be limited by any theoretical explanation, it is believed that the family of substances known as the inositols, are physiological precursors to membrane protein anchors known as glycosphatidylinositols (GPI). As used herein, "inositols" includes myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, d-pinitol and myo-inositol. Hydrolysis of GPI releases in inositolphosphoglycans which are water soluble mediators of insulin signalling events. Accordingly, increased availability of these GPI precursors, increase insulin sensitivity and these GPIs can trigger insulin signalling pathways and events independent of insulin thereby mimicing the effects of insulin. The pathways and events which are mimiced include, but are not limited to amino acid transport, protein synthesis, gene transcription, mRNA translation initiation, glucose uptake, glycogen storage, steroid hormones synthesis, and can thereby increase the development of muscle cells. Consequently, supplements which comprise a substance which can enhance and/or mimic insulin activity, and a source of amino acids, preferably any source of protein, more preferably, whey, may provide further and significant muscle size and strength enhancement as compared with supplements employing only proteins or amino acids.

The food supplements described herein comprise the compounds specifically identified and any derivatives thereof, for example a salt or ester. Suitable salts include, but are not limited to, alkali and alkaline earth metal salts, for example sodium, potassium or calcium salts, while suitable esters include, but are not limited to, alkyl esters, for example, methyl, ethyl or propyl esters, or lactone esters.

As used herein "source of amino acid" means any peptide, polypeptides, protein or any composition of individual amino acids or

individual amino acid. Throughout the present specification, as a part of the food supplement of the invention whey protein or a derivative thereof are identified as the preferred source of amino acids or protein. Commercially available whey protein derivatives include WPI 97,
5 Whey Peptides, WPC 80, and ION EXCHANGE whey protein. However, as will be readily appreciated by those skilled in the art, other sources of protein include milk protein, casein, any of the albumins including chicken egg albumin, and soy, may be used as a source of amino acids.

10 **Supplements**

According to one embodiment of the present invention there is provided a food supplement comprising a substance which increases nitric oxide production in the body in combination with a source of amino acids. As used herein, "a food supplement comprising a
15 substance ... in combination with a source of amino acids" means the supplement contains both the substance which has an action as well as a source of amino acids. According to one aspect, an increase in nitric oxide production may be brought about by a substance selected from the group consisting of glycosidal saponins, ginseng, l-arginine, folic
20 acid, bioflavonoids, for example, grape seed extract, and herbs, preferably l-arginine, most preferably ginseng.

According to one aspect of the present invention a substance which increases nitric oxide production may act by stimulating insulin levels in the circulation, preferably, the substance is selected
25 from the group consisting of L-arginine, glycosidal saponins, for example, ginseng, and N-acetyl cysteine, most preferably ginseng.

According to another embodiment of the present invention, there is provided a food supplement comprising a substance which mimics and/or enhances insulin activity, the supplement also
30 containing a source of amino acids. According to a preferred embodiment, a substance which mimics and/or enhances insulin activity is preferably selected from the group consisting of N-acetyl

cysteine, myo-inositol, preferably d-myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, d-pinitol and glucomannan, most preferably glucomannan.

5 A source of amino acids is preferably selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, whey protein, most preferably whey protein, although as indicated above, any other protein source may be used.

10 According to yet another aspect of the present invention, there is provided a supplement which may increase nitric oxide thereby increasing nitrogen retention in the body. Preferably the supplement comprises a substance which may increase nitrogen retention in the body, in combination with a source of amino acids. Preferably the
15 substance which may increase nitrogen retention in the body is selected from the group consisting of glucomannan, glycosidal saponins, for example, ginseng, l-arginine, glutamine, methionine and leucine, preferably glucomannan, most preferably ginseng. The source of amino acids is preferably selected from the group consisting of WPI
20 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, whey protein, most preferably whey protein.

 As will be readily appreciated by those skilled in the art, the supplement is not limited to only one substance which by itself may increase nitric oxide, insulin output, insulin secretion, insulin sensitivity, and one source of amino acids. Indeed the present
25 invention provides for combinations of substances and sources of amino acids, in differing amounts.

 The food supplement compositions of the present invention may be provided in a variety of formats, for example, in liquid form, powder form, or protein bar form. Powders are preferable and are
30 prepared to be suitable for mixing with water or other liquids. The food supplement compositions in powder or granular form may be provided in accordance with customary processing techniques, for

example as spray dried powders, or the like.

According to one embodiment, the food supplement compositions of the present invention are delivered in powder on a per one "scoop" basis. As used herein, one "scoop" is approximately 28 g of supplement. According to one embodiment, one "scoop" comprises: glycosidal saponins (such as ginseng) from 1mg-3000 mg; myo-inositol, from 1mg- 2000mg; d-chiro-inositol, from 1mg-2000mg; and glucomannan, from 10mg-4000mg; and a source of amino acids, preferably protein, most preferably whey.

According to another embodiment a food supplement composition comprises, when delivered in powder form per one "scoop": glycosidal saponins, about 150mg to about 1500mg; myo-inositol about 100mg to about 2000mg; and glucomannan from about 25mg to about 2000mg; and a source of amino acids, preferably protein, most preferably whey.

According to another embodiment the food supplement composition comprises, when delivered in powder form per one "scoop": glycosidal saponins from about 50mg to about 500mg; glucomannan from about 50mg to about 1000mg; and myo-inositol, from about 200mg to about 1000mg, and a source of amino acids preferably protein, most preferably whey.

According to another embodiment, the food supplement composition comprises, when delivered in powder form per one "scoop": glucomannan from about 100mg to about 500mg; and a source of amino acids, preferably protein, most preferably whey.

According to yet another embodiment, the food supplement composition comprises, when delivered in powder form per one "scoop" glycosidal saponins at about 50mg; and a source of amino acids, preferably protein, most preferably whey.

The food supplement compositions according to the present invention may further contain additional components to further increase the speed and or ease with which the substances enter the

bloodstream and subsequently possibly impact the muscle tissue, or to otherwise enhance the effects of nitric oxide in the body. For example, additional amino acids may be included in the food supplement compositions. Suitable amino acids include, but are not limited to, glutamine, alanine, taurine, carnitine, acetyl-L-carnitine, and the like. These additional amino acids may stimulate cell volumization and protein synthesis and therefore provide further advantages to increasing muscle strength and/or size. These amino acids may be employed individually or in various combinations and in amounts customary in the art, for example in the range of from about 0.01 mg to about 1000 mg per gram of food supplement depending upon the amount of protein, or peptides, derived from whey or other source of amino acid in the supplement.

The food supplement compositions can also contain ascorbic acid (vitamin C), for example in amounts equal to or exceeding the recommended minimum daily requirements. Another component for possible use in the food supplements of the present invention comprises beta-hydroxy, beta-methyl butyrate (HMB), in amounts known in the art.

The food supplement compositions may further comprise natural and/or artificial flavouring components, dyes or other colouring additives, preservatives and other conventional food supplement additives known in the art.

Methods of Use of Supplements

The food supplements according to the present invention may be employed in methods for supplementing the diet of an athlete, and/or for enhancing an athlete's muscle size or strength. The food supplement compositions of the present invention are particularly advantageous for creating an increased anabolic environment and obtaining extra growth in lean muscle mass and strength. Accordingly, the present invention provides methods of supplementing bodybuilding in an athlete comprising administering

to the athlete an effective amount of a food supplement according to the present invention. Administration of an "effective amount" of the supplements and substances of the present invention is defined as an amount effective, at dosages and for periods of time necessary to
5 achieve the desired result. The effective amount of the supplements of the invention may vary according to factors such as the age, sex, and weight of the athlete. Dosage regima may be adjusted to provide the optimum response: Several divided doses may be administered daily or the dose may be proportionally reduced as indicated by the
10 exigencies of the individual athlete situation.

As just stated, the amount of the food supplement composition which is administered to the diet of the athlete may vary depending on the desired effect, the body weight and characteristics of the athlete, and the like. For example, in preferred methods for supplementing
15 the diet of an athlete and/or for enhancing an athlete's muscle size or strength, from about 0.5 to about 10 scoops of a supplement according to present invention are administered to the diet of the athlete on a daily basis.

In more preferred embodiments of these methods, from about 1
20 to about 6 scoops of a supplement according to the present invention are administered to the diet of the athlete on a daily basis. Number of scoops and frequency per day will depending upon the composition of the scoop, as outlined in variations set out above.

As will be readily appreciated a food supplement in accordance
25 with the present invention may be administered in a single serving or in multiple servings spaced throughout the day. In a preferred embodiment, a food supplement in accordance with the present invention may be administered once in the morning, once immediately or shortly after training and once in the evening on a
30 daily basis.

In order to maximize the effects of a food supplement according to the present invention, in enhancing muscle size and/or strength, it

is preferred that the food supplement is administered to the diet of the athlete immediately following an exercise period. On non-workout days, the food supplement may be administered anytime during the day, although administering a first amount of a food supplement upon awakening or otherwise during the morning hours is preferred.

The food supplement compositions and methods of the invention are further illustrated in the following non-limiting examples. In the examples and throughout the present specification, parts and percentages are by weight unless otherwise specified.

10

EXAMPLES

EXAMPLE 1

A muscle size and/or strength enhancing regime is initiated and established so that the athlete consumes three servings of the following food supplement daily, with each serving being 1 scoop which is approximately 28 g of the supplement and comprising:

15

Per 1 scoop:

Protein	20g
Carbohydrates	3g
Fiber	1g
Sugar	2g
Fat:	1.5g

20

INGREDIENT

AMOUNT/SERVING

SyntheProTMA blend of the following constituting 18g

WPI 97

25

WHEY PEPTIDES

WPC 80

ION EXCHANGE WHEY

LACTOFERRIN

NitroxenTM A blend of the following constituting

30

ARGININE

GLYCOSIDAL SAPONINS

	FOLIC ACID	400mcg
	Insulogen™ A blend of the following constituting	200mg
	MYO-INOSITOL,	
	CIS-INOSITOL	
5	EPI-INOSITOL	
	ALLO-INOSITOL	
	MUCO-INOSITOL	
	NEO-INOSITOL	
	SCYLLO-INOSITOL	
10	D-CHIRO-INOSITOL	
	L-CHIRO-INOSITOL	
	INZITOL((D-PINITOL)	
	GLUCOMANNAN	
	TAURINE	100mg
15	LEUCINE	
	POTASSIUM PHOSPHATE	100mg
	VIT E	30IU
	NAC	25mg
	VIT B6	10.5mg
20	MAGNESIUM	50mg
	The rest of the volume comprising the following:	
	GUAR GUM	
	METHIONINE	
	GLUTAMINE PEPTIDES	
25	GLUTAMINE	
	ALPHA-KETO GLUTARATE	
	PHENYLALANINE	

Each supplement serving is mixed with 6 ounces of cold water and the servings are administered approximately evenly spaced through the day, with a first serving in the morning, shortly after awakening, a second serving being consumed immediately after the athlete's exercise workout, and a third at a convenient time in the

evening.

EXAMPLE 2

A muscle size and/or strength enhancing regime as outlined in Example 1 is established so that the athlete consumes three servings of the food supplement daily, with each serving being 2 scoops which is approximately 56 g of the supplement.

EXAMPLE 3

Where the regime in Example 1 or 2 is established, the athlete continues this regime on a day-to-day basis. As in Example 1 or 2, the serving is mixed with cold water to form a liquid drink. Alternatively, the food supplements may be combined with other liquid drinks or foods as desired. This regime is intended to last for the full term during which an athlete is working out. The servings and their timing should also be consumed on non-workout days (with the second serving being taken mid-day) in order to maintain enhanced muscle size and/or strength.

The servings set forth in these examples are designed for a 2000 calorie diet. Daily values may be increased or decreased depending on the calorie needs of individual athletes, and/or body weights of individual athletes.

EXAMPLE 4

Thirty-six experienced weight trained males were randomly assigned (double-blind) to one of three experimental groups: 1. a dietary supplement of a whey protein blend, comprising whey protein isolate 97%, creatine, glycosidal saponins, arginine, and glucomannan (WI) - 1.2 g/kg/d whey protein, and 0.1 g/kg/d creatine; pure whey protein (W) - 1.2 g/kg/d; or a placebo (P) - 1.2 g/kg/d maltodextrin. Pre and post test measures consisted of 1-RM bench press, 1-RM squat, Biodex isokinetic leg extension power (ILP), and body composition as assessed

- by dual energy x-ray absorptiometry (DEXA). Training involved a 4-day split routine of high volume, heavy load periodized workouts with sets and reps varying from 4-5 sets and 4-10 reps. Each group experienced a significant change from baseline measure ($p < 0.05$). Post
- 5 hoc analysis revealed that the WI group demonstrated greater increases in lean muscle mass (+4.0 kg), 1-RM bench press (+16 kg), and ILP (+23 J/s) than W and P ($p < 0.05$). The W group had a significantly greater increase in lean mass (+2.3 kg) and ILP (+18 J/s) than the P group ($p < 0.05$). These findings indicate that whey protein
- 10 supplementation when combined with resistance training for 6-weeks results in significant gains in muscular power and lean muscle mass, and when the whey protein is combined with other potentially ergogenic acids, even larger gains in muscle mass, 1-RM strength, and power occur.
- 15 The examples and embodiments set forth in the present application are provided only to illustrate various aspects of the invention and additional embodiments and advantages of the food supplements and methods of the present invention will be apparent to those skilled in the art.

I CLAIM:

1. A food supplement comprising a substance which increases nitric oxide production in the body, and, a source of amino acids.
2. A food supplement according to claim 1 wherein the substance which increases nitric oxide production is selected from the group consisting of glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, and folic acid.
3. A food supplement according to claim 2 wherein the substance is ginseng.
4. A food supplement which comprises a substance which can enhance and/or mimic insulin activity, and a source of amino acids.
5. A food supplement according to claim 4 wherein the substance is glucomannan.
6. A food supplement according to claim 4 wherein the substance is selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol.
7. A food supplement according to claim 6 wherein the substance is myo-inositol.
8. A supplement which increases nitrogen retention in the body comprising a substance which increases nitrogen retention and a source of amino acids.
9. A supplement according to claim 8 wherein the substance

which increases nitrogen retention in the body is selected from the group consisting of glucomannan and l-arginine.

10. A supplement according to claim 9 wherein the substance is glucomannan.
- 5 11. A supplement comprising a glycosidal saponin, glucomannan D-chiro-inositol, myo-inositol, and a source of amino acids.
12. A supplement comprising a glycosidal saponin, glucomannan myo-inositol, and a source of amino acids.
- 10 13. A supplement according to any one of claims 1 to 12 wherein the source of amino acids is selected from the group consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, and whey protein.
14. A food supplement comprising a substance which increases nitric oxide production in the body, and, whey protein.
- 15 15. A supplement according to claim 14 wherein the whey protein is WPI 97, Whey Peptides, WPC 80, or ION EXCHANGE whey protein.
16. A supplement according to claim 14 wherein the whey protein is a combination of two or more of WPI 97, Whey Peptides, WPC 80, or ION EXCHANGE whey protein.
- 20 17. A food supplement according to claim 14 wherein the substance which increases nitric oxide production is selected from the group consisting of glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine and folic acid.

18. A food supplement according to claim 17 wherein the substance is ginseng.
19. A food supplement comprising 1mg-3000 mg glycosidal saponins; 1mg-2000mg myo-inositol; 1mg-2000mg d-chiro-inositol;
5 10mg-4000mg glucomannan; and a source of amino acids.
20. A food supplement according to claim 19 wherein the glycosidal saponins comprise 150mg to 1500mg; the myo-inositol comprises about 100mg to 2000mg; and the glucomannan comprises 25 mg to 2000mg.
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21. A food supplement according to claim 19 wherein the glycosidal saponins comprise 50mg to 500mg; the myo-inositol comprises about 200mg to 1000mg; and the glucomannan comprises 50mg to 1000mg.
22. A food supplement according to claim 19 wherein the
15 glucomannan comprises 100mg to 500mg.
23. A food supplement according to claim 19 wherein the glycosidal saponins comprise about 50mg.
24. A food supplement according to anyone of claims 19-23 wherein the source of amino acids is whey protein.
- 20 25. A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of a supplement comprising a substance which increases nitric oxide production in the body and a source of amino acids.
26. A method according to claim 25 wherein the the substance
25 which increases nitric oxide production is selected from the group

consisting of glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, and folic acid.

27. A method according to claim 26 wherein the substance is ginseng.

5 28. A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of a supplement comprising a substance which can enhance and/or mimic insulin activity, and a source of amino acids.

10 29. A method according to claim 28 wherein the substance is glucomannan.

30. A method according to claim 28 wherein the substance is selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol.

15 31. A method according to claim 30 wherein the substance is myo-inositol.

32. A method according to claim 31, wherein the supplement is administered to the diet of the athlete on a daily basis.

20 33. A method according to claim 32, wherein the food supplement is mixed with water to provide a liquid drink.

34. A method for increasing muscle mass and or strength of an individual, comprising administering to the diet of the athlete an effective amount of a supplement a substance which increases nitric oxide production in the body and a source of amino acids.

35. A method according to claim 34 wherein the the substance which increases nitric oxide production is selected from the group consisting of glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, and folic acid.

5 36. A method according to claim 35 wherein the substance is ginseng.

37. A method for increasing muscle mass and or strength of an individual comprising administering to the diet of the athlete an effective amount of a supplement comprising a substance which can
10 enhance and/or mimic insulin activity, and a source of amino acids.

38. A method according to claim 37 wherein the substance is glucomannan.

39. A method according to claim 37 wherein the substance is selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol,
15 scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol.

40. A method according to claim 39 wherein the substance is myo-inositol.

41. A method according to claim 40 wherein the supplement is
20 administered to the diet of the athlete on a daily basis.

42. A method according to claim 41 wherein the food supplement is mixed with water to provide a liquid drink.

43. A method for supplementing the diet of an athlete, comprising

administering to the diet of the athlete an effective amount of a supplement comprising a substance which increases nitric oxide production in the body and whey protein.

5 44. A method according to claim 43 wherein the substance which increases nitric oxide production is selected from the group consisting of glycosidal saponins, ginseng, l-arginine, N-acetyl cysteine, and folic acid.

45. A method according to claim 44 wherein the substance is ginseng.

10 46. A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of a supplement comprising a substance which can enhance and/or mimic insulin activity, and whey protein.

15 47. A method according to claim 46 wherein the substance is glucomannan.

48. A method according to claim 46 wherein the substance is selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol.

20 49. A method according to claim 48 wherein the substance is myo-inositol.

50. A method according to claim 48, wherein the supplement is administered to the diet of the athlete on a daily basis.

51. A method according to claim 50, wherein the food supplement

is mixed with water to provide a liquid drink.

52. A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of a supplement comprising 1mg-3000 mg glycosidal saponins; 1mg-
5 2000mg myo-inositol; 1mg-2000mg d-chiro-inositol; 10mg-4000mg glucomannan; and a source of amino acids.

53. A method according to claim 52 wherein the glycosidal saponins comprise 150mg to 1500mg; the myo-inositol comprises about 100mg to 2000mg; and the glucomannan comprises 25 mg to 2000mg.

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54. A method according to claim 52 wherein the glycosidal saponins comprise 50mg to 500mg; the myo-inositol comprises about 200mg to 1000mg; and the glucomannan comprises 50mg to 1000mg.

55. A method according to claim 52 wherein the glucomannan
15 comprises 100mg to 500mg.

56. A method according to claim 52 wherein the glycosidal saponins comprise about 50mg.

57. A method according to anyone of claims 52-56 wherein the source of amino acids is whey protein.

ABSTRACT

Food supplement compositions and their methods of use in increasing lean mass and/or muscle size and/or strength in individuals, particularly, athletes is described. The food supplements
5 described comprise a substance which increases nitric oxide production in the body, and, a source of amino acids. Other food supplements described comprise a substance which can enhance and/or mimic insulin activity, and a source of amino acids. The food supplement
10 compositions described are suitable for supplementing the diet of an athlete and particularly for enhancing an athlete's muscle size or strength.

DECLARATION
and
POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **Food Supplement for Increasing Lean Mass and Strength**, the specification of which

☒ is attached hereto.

☐ was filed on _____ as application serial no. _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim U.S. provisional application or foreign priority benefits under Title 35, United States Code, §119 of any U.S. provisional applications or any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior U.S. Provisional or Foreign Application(s)				
			Priority Claimed	
Number	Country	Day/Month/Year Filed	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulation, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

09/420,439	October 18, 1999	Pending
(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

(Application Serial No.)	(Filing Date)	(Status)
		(patented, pending, abandoned)

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The undersigned hereby authorizes the above-named U.S. attorneys to accept and follow instructions from Bereskin & Parr as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the undersigned and the aforementioned U.S. attorneys. In the event of a change in the firm or persons from whom instructions may be taken, the aforementioned U.S. attorneys will be so notified in writing by the undersigned.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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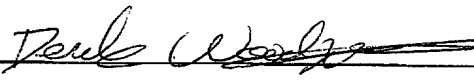
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